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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/611,533	06/30/2003	Scott A. Waldman	100051.11211	4518
35148 7590 09/25/2008 Pepper Hamilton LLP 400 Berwyn Park 899 Cassatt Road Berwyn, PA 19312-1183				
EXAMINER				
YU, MISOOK				
ART UNIT		PAPER NUMBER		
1642				
MAIL DATE		DELIVERY MODE		
09/25/2008		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/611,533

**Applicant(s)**

WALDMAN ET AL.

**Examiner**

MISOOK YU

**Art Unit**

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 30 June 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-3, 8-13, 19, 20, 29-31 and 39-48 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3, 8-13, 19, 20, 29-31, 39, 41, 42, 44, 45, 47 and 48 is/are rejected.
- 7) ☒ Claim(s) 40, 43 and 46 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-849)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 06/30/2008 has been entered.

Claims 1-3, 8-13, 19, 20, 29-31, and 39-48 are pending and examined on merits.

The rejection of record set forth in the Office action mailed on 01/29/2008 is withdrawn because applicant's argument is persuasive. This Office action contains new grounds of rejection.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Claim Objections***

Claims 41, 42, 44, 45, 47, and 48 are objected to because of the following informalities: The incorporation of essential material in the specification by reference to a foreign application or patent, or to a publication is improper. The claims define the invention Genbank accession numbers. The marker sequences are essential to practice the claimed invention, and the only disclosure of the sequences is made by references to published information outside of the specification. Therefore, information essential to practice the invention is incorporated by reference. In addition, Genbank

accession numbers are constantly updated and it is not clear the scope of the invention as time goes by. It would not clear to whether the updated information after the filing date is also included in the claimed invention. Applicant is required to amend the disclosure to include the material incorporated by reference. The amendment must be accompanied by an affidavit or declaration executed by the applicant, or a practitioner representing the applicant, stating that the amendatory material consists of the same material incorporated by reference in the referencing application. See *In re Hawkins*, 486 F.2d 569, 179 USPQ 157 (CCPA 1973); *In re Hawkins*, 486 F.2d 579, 179 USPQ 163 (CCPA 1973); and *In re Hawkins*, 486 F.2d 577, 179 USPQ 167 (CCPA 1973).

***Claim Rejections - 35 USC § 112***

Claims 41, 42, 44, 45, 47, and 48 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claimed Genbank accession nos are critical or essential to the practice of the invention, but not included in the claim(s) is not enabled by the disclosure. The Web site could be closed down permanently in the future although it is a remote possibility now but it could happen. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976). In order to practice the invention claimed, one of skill has to know the claimed Genbank accession numbers incorporated by reference. An amendment accompanied by an affidavit or declaration executed by the applicant, or a practitioner representing

the applicant, stating that the amendatory material consists of the same material incorporated by reference in the referencing application would obviate this part of rejection. See *In re Hawkins*, 486 F.2d 569, 179 USPQ 157 (CCPA 1973); *In re Hawkins*, 486 F.2d 579, 179 USPQ 163 (CCPA 1973); and *In re Hawkins*, 486 F.2d 577, 179 USPQ 167 (CCPA 1973).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-3, 8-13, 19, 20, 29-31, and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Silberg et al., *Gastroenterology*, 1997 Aug;113(2):478-86 in view of US 5601990 A (the '990 patent, issue date of Feb. 11, 1997).

Claims 1-3, 8-13, 19, 20, 29-31, and 39 are drawn to method of screening an individual for metastatic colorectal, stomach or esophageal cancer comprising detection of CDX1 in extraintestinal tissue and/or body fluids, wherein transcription products is detected in claim 2.

Silberg et al., teach CDX1 protein is detected in stomach or esophageal cancer tissue.

However, Silberg et al., does not teach a method of detection of the biomarker in extraintestinal tissue and/or body fluids.

However, US 5601990 teaches extraintestinal tissue (lymph node, note paragraph 31) and/or body fluids is used to detect a biomarker and the detection of such biomarker for cancer is associated with metastasis. Also note claims.

Therefore, it would have been obvious to one of ordinary skill in the art to arrive at the claimed invention with a reasonable expectation of success since Silberg et al., teach that CDX1 is a biomarker "involved in the neoplastic process" (note page 479) of "Alimentary Tact Epithelium" (note the title) and US 5601990 A teaches how to use extraintestinal tissue and/or body fluids for a biomarker for metastatic cancers.

One of skill in the art would have been motivated to arrive at the claimed invention because US 5601990 at paragraph 6 teaches "diagnosis of metastatic or recurrent disease earlier potentially carries with it a better prognosis".

Claims 41, 44, and 47 are rejected under **35 U.S.C. 103(a)** as being unpatentable over Silberg et al., (cited above) in view of US 5601990 A as applied to claims 1, 11, and 29 above, and further in view of GenBank Accession no. U51095 (Applicant provided a copy with the reply filed on 06/30/2008, 14-Jan-1997).

Note what Silberg et al., and US 5601990 A teach above.

Neither Silberg et al., nor US 5601990 A teach the claimed GenBank Accession no. U51095.

However, the GenBank Accession no. U51095 was known well before the effective filing date. Thus, this sequence would have been recognized by one of ordinary skill in the art as CDX1 of Silberg et al., above.

Therefore it would have been obvious to one of skill in the art to arrive at the claimed invention with a reasonable expectation of success since GenBank Accession no. U51095 teaches the necessary sequence information to make probes for the diction.

Claims 42, 45, and 48 are rejected under **35 U.S.C. 103(a)** as being unpatentable over Silberg et al., (cited above) in view of US 5601990 A as applied to claims 1, 11, and 29 above, and further in view of GenBank Accession no. U15212 (Applicant provided a copy with the reply filed on 06/30/2008, 14-Jan-1997).

Note what Silberg et al., and US 5601990 A teach above.

Neither Silberg et al., nor US 5601990 A teach the claimed GenBank Accession no. U15212.

However, the GenBank Accession no. U15212 was known well before the effective filing date. Thus, this sequence would have been recognized as CDX1 of Silberg et al., above.

Therefore it would have been obvious to one of skill in the art to arrive at the claimed invention with a reasonable expectation of success since GenBank Accession no. U15212 teaches the necessary sequence information to make probes for the diction.

### ***Conclusion***

Claims 40, 43, and 46 are objected to as being dependent upon a rejected base claim.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MISOOK YU whose telephone number is 571-272-0839. The examiner can normally be reached on 8 A.M. to 5:30 P.M., every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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